Complete Summary

GUIDELINE TITLE

Drug misuse: opioid detoxification.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Drug misuse: opioid detoxification. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007. 276 p. (Clinical practice guideline; no. 52). [251 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Opioid misuse

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics

Psychiatry
Psychology

INTENDED USERS

Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

- To advise on opioid detoxification for drug misuse
- To evaluate the role of opioid detoxification in the treatment of drug misuse
- To evaluate the role of specific psychosocial interventions in combination with opioid detoxification in the treatment of drug misuse
- To integrate the above to provide best practice advice on the care of individuals throughout the course of their drug misuse
- To promote the implementation of best clinical practice through the development of recommendations tailored to the requirements of the National Health Service (NHS) in England and Wales

TARGET POPULATION

Adults and young people (adolescents 16-18 years old) who are dependent on opiates and have been identified as suitable for a detoxification programme

INTERVENTIONS AND PRACTICES CONSIDERED

Management

1. Providing information about detoxification and obtaining informed consent
2. Offering advice on aspects of lifestyle that need attention
3. Developing and monitoring care plan in conjunction with service user
4. Providing information about 12-step programs
5. Discussing involvement of family and carers
6. Supporting family and carers

Assessment and Testing

1. Clinical assessment including:
    - Urinalysis
    - Assessment of symptoms of withdrawal
    - History of drug and alcohol misuse and treatment
    - Current and previous physical and mental health issues
    - Consideration of risks of treatment, social and personal circumstances, and impact on family

- Development of strategies to reduce risk of relapse

2. Confirmatory laboratory testing, if necessary
3. Consideration of special situations

Treatment

Pharmacologic Interventions

1. Methadone or buprenorphine (lofexidine is also an option)
2. Clonidine and dihydrocodeine were considered but should not be routinely used
3. Consideration of dosage and duration
4. Ultra-rapid, rapid detoxification, and accelerated detoxification should not be routinely offered
5. Adjunctive medications
6. Monitoring of medication

Setting

1. Consideration of community, inpatient, residential, and prison-based
2. Continued support, regardless of setting

Psychosocial Interventions

Contingency management

MAJOR OUTCOMES CONSIDERED

- Duration of abstinence
- Rate of treatment completion
- Rate of adverse events
- Severity of withdrawal
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Clinical Questions

Clinical questions were used to guide the identification and interrogation of the evidence base relevant to the topic of the guideline. Before the first Guideline Development Group (GDG) meeting, draft questions were prepared by National

Collaborating Centre for Mental Health (NCCMH) staff based on the scope and an overview of existing guidelines. They were then discussed by the GDG at their first two meetings and amended as necessary. Where appropriate, the questions were refined once the evidence had been searched and, where necessary, sub-questions were generated. The final list of clinical questions can be found in Appendix 7 of the original guideline document.

For questions about interventions, the PICO (patient, intervention, comparison, and outcome) framework was used. This structured approach divides each question into four components: the patients (the population under study), the interventions (what is being done), the comparisons (other main treatment options), and the outcomes (the measures of how effective the interventions have been) (See Text Box 2 of the original guideline document.)

Questions relating to diagnosis did not involve an intervention designed to treat a particular condition, therefore the PICO framework was not used. Rather, the questions were designed to pick up key issues specifically relevant to diagnostic tests, for example their accuracy, reliability, safety, and acceptability to the patient.

In some situations the prognosis of a particular condition was of fundamental importance, over and above its general significance in relation to specific interventions. Areas where this was particularly likely to occur relate to assessment of risk, for example in terms of behaviour modification or screening and early intervention. In addition, questions related to issues of service delivery were occasionally specified in the remit from the Department of Health (DH)/Welsh Assembly Government. In these cases, appropriate clinical questions were developed to be clear and concise.

To help facilitate the literature review, a note was made of the best study design type to answer each question. There are four main types of clinical question of relevance to National Institute for Health and Clinical Excellence (NICE) guidelines. For each type of question, the best primary study design varies, where 'best' is interpreted as 'least likely to give misleading answers to the question'.

However, in all cases, a well-conducted systematic review of the appropriate type of study was likely to always yield a better answer than a single study.

Deciding on the best design type to answer a specific clinical or public health question did not mean that studies of different design types addressing the same question were discarded.

Systematic Clinical Literature Review

The aim of the clinical literature review was to systematically identify and synthesise relevant evidence from the literature in order to answer the specific clinical questions developed by the GDG. Thus, clinical practice recommendations are evidence based, where possible, and, if evidence is not available, informal consensus methods are used (see Section 3.5.6 of the original guideline document) and the need for future research is specified.

Methodology

A stepwise, hierarchical approach was taken to locating and presenting evidence to the GDG. The NCCMH developed this process based on methods set out in *The Guidelines Manual* (see the "Availability of Companion Documents" field below) and after considering recommendations from a range of other sources. These included:

- Centre for Clinical Policy and Practice of the New South Wales Department of Health
- Clinical Evidence Online
- The Cochrane Collaboration
- Grading of Recommendations: Assessment, Development, and Evaluation (GRADE) Working Group
- New Zealand Guideline Group
- National Health Service (NHS) Centre for Reviews and Dissemination
- Oxford Centre for Evidence-Based Medicine
- Oxford Systematic Review Development Programme
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Agency for Healthcare Research and Quality

The Review Process

After the scope was finalised, a more extensive search for systematic reviews and published guidelines was undertaken. Existing NICE guidelines were updated where necessary. Other relevant guidelines were assessed for quality using the AGREE instrument, and the evidence base underlying high-quality guidelines was utilised and updated as appropriate.

At this point, the review team, in conjunction with the GDG, developed a review protocol that detailed all comparisons necessary to answer the clinical questions. The initial approach taken to locating primary-level studies depended on the type of clinical question and availability of evidence.

The GDG decided which questions were best addressed by good practice based on expert opinion, which questions were likely to have a good evidence base and which questions were likely to have little or no directly relevant evidence. Recommendations based on good practice were developed by informal consensus of the GDG. For questions with a good evidence base, the review process depended on the type of key question (see below). For questions that were unlikely to have a good evidence base, a brief descriptive review was initially undertaken by a member of the GDG.

Searches for evidence were updated 6–8 weeks before the stakeholder consultation. After this point, studies were included only if they were judged by the GDG to be exceptional (for example, the evidence was likely to change a recommendation).

The Search Process for Questions Concerning Interventions

For questions related to interventions, the initial evidence base was formed from well-conducted randomised controlled trials (RCTs) that addressed at least one of the clinical questions. Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in mental health, the RCT remains the most important method for establishing treatment efficacy (this is discussed in more detail in appropriate clinical evidence chapters). For other clinical questions, searches were for the appropriate study design.

All searches were based on the standard mental health related bibliographic databases (EMBASE, MEDLINE, PsycINFO, Cochrane Library, CINAHL) for all trials potentially relevant to the guideline. The search was not restricted to English languages publication but included papers from other languages where native speakers were available to translate.

Where the evidence base was large, recent high-quality English-language systematic reviews were used primarily as a source of RCTs (see Appendix 10 of the original guideline document for quality criteria used to assess systematic reviews). However, in some circumstances existing data sets were utilised. Where this was the case, data were cross-checked for accuracy before use. New RCTs meeting inclusion criteria set by the GDG were incorporated into the existing reviews and fresh analyses performed.

After the initial search results were scanned liberally to exclude irrelevant papers, the review team used a purpose-built 'study information' database to manage both the included and the excluded studies (eligibility criteria were developed after consultation with the GDG). For questions without good-quality evidence (after the initial search), a decision was made by the GDG about whether to (a) repeat the search using subject-specific databases (for example, AMED, SIGLE or PILOTS), (b) conduct a new search for lower levels of evidence or (c) adopt a consensus process (see Section 4.5.6 of the original guideline document).

In addition, searches were made of the reference lists of all eligible systematic reviews and included studies, as well as the list of evidence submitted by stakeholders. Known experts in the field (see Appendix 6 of the original guideline document), based both on the references identified in early steps and on advice from GDG members, were sent letters requesting relevant studies that were in the process of being published. In addition, the tables of contents of appropriate journals were periodically checked for relevant studies.

The Search Process for Questions of Diagnosis and Prognosis

For questions related to diagnosis and prognosis, the search process was the same as described above, except that the initial evidence base was formed from studies with the most appropriate and reliable design to answer the particular question. That is, for questions about diagnosis, the initial search was for cross-sectional studies; for questions about prognosis, it was for cohort studies of representative patients. In situations where it was not possible to identify a substantial body of appropriately designed studies that directly addressed each clinical question, a consensus process was adopted (see Section 4.5.6 of the original guideline document).

Search Filters

Search filters developed by the review team consisted of a combination of subject heading and free-text phrases. Specific filters were developed for the guideline topic and, where necessary, for each clinical question. In addition, the review team used filters developed for systematic reviews, RCTs and other appropriate research designs (Appendix 8 of the original guideline document).

Study Selection

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the study information database. Eligibility criteria were developed for each clinical question and are described in the relevant clinical evidence chapters. Eligible systematic reviews and primary-level studies were critically appraised for methodological quality (see Appendix 10 and Appendix 15 [the characteristics of included studies tables] in the original guideline document). The eligibility of each study was confirmed by at least one member of the appropriate topic group.

For some clinical questions, it was necessary to prioritise the evidence with respect to the United Kingdom (UK) context (that is, external validity). To make this process explicit, the topic groups took into account the following factors when assessing the evidence:

- Participant factors (for example, gender, age, and ethnicity)
- Provider factors (for example, model fidelity, the conditions under which the intervention was performed and the availability of experienced staff to undertake the procedure)
- Cultural factors (for example, differences in standard care and differences in the welfare system)

It was the responsibility of each topic group to decide which prioritisation factors were relevant to each clinical question in light of the UK context and then decide how it should modify its recommendations.

Unpublished Evidence

The GDG used a number of criteria when deciding whether or not to accept unpublished data. First, the evidence must have been accompanied by a trial report containing sufficient detail to properly assess the quality of the data. Second, the evidence must have been submitted with the understanding that data from the study and a summary of the study's characteristics would be published in the full guideline (therefore, the GDG did not accept evidence submitted as commercial in confidence). However, the GDG recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

Cost-Effectiveness Search Strategy

Refer to section 4.6 of the full version of the original guideline document for details of the systematic economic literature review, including search strategy and selection criteria.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

Level of Evidence	Type of Evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs) or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1−	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias*
2++	High-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2−	Case–control or cohort studies with a high risk of confounding bias or chance and a significant risk that the relationship is not causal*
3	Non-analytic studies (for example, case reports and case series)
4	Expert opinion, consensus methods

*Studies with a level of evidence '−' should not be used as a basis for making a recommendation

Quality of Evidence

The quality of the evidence was based on the quality assessment components (study design, limitations to study quality, consistency, directness and any other considerations) and graded using the following definitions:

- **High** = Further research is very unlikely to change confidence in the estimate of the effect.
- **Moderate** = Further research is likely to have an important impact on confidence in the estimate of the effect and may change the estimate.
- **Low** = Further research is very likely to have an important impact on confidence in the estimate of the effect and is likely to change the estimate.

- **Very low** = Any estimate of effect is very uncertain.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction and Synthesising the Evidence

Outcome data were extracted from all eligible studies that met the quality criteria. Where possible, meta-analysis was used to synthesise the evidence using Review Manager 4.2.8. If necessary, reanalyses of the data or sub-analyses were used to answer clinical questions not addressed in the original studies or reviews.

Where possible, dichotomous efficacy outcomes were calculated on an intention-to-treat basis (that is, a 'once-randomised-always-analyse' basis). This assumes that those participants who ceased to engage in the study—from whatever group—had an unfavourable outcome. Adverse effects were entered into Review Manager as reported by the study authors because it was usually not possible to determine whether early withdrawals had an unfavourable outcome. For the outcome 'leaving the study early for any reason', the denominator was the number randomised.

Included/excluded studies tables, generated automatically from the study information database, were used to summarise general information about each study (see Appendix 15 of the original guideline document). Where meta-analysis was not appropriate and/or possible, the reported results from each primary-level study were also presented in the included studies table (and included, where appropriate, in a narrative review).

Consultation was used to overcome difficulties with coding. Data from studies included in existing systematic reviews were extracted independently by one reviewer and cross-checked with the existing data set. Where possible, two independent reviewers extracted data from new studies. Where double data extraction was not possible, data extracted by one reviewer was checked by the second reviewer. Disagreements were resolved with discussion. Where consensus could not be reached, a third reviewer resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution and the magnitude of the effect) was not used since it is unclear that doing so reduces bias.

Presenting the Data to the Guideline Development Group (GDG)

Summary characteristics tables and, where appropriate, forest plots generated with Review Manager were presented to the GDG in order to prepare an evidence profile for each review and to develop recommendations.

Evidence Profile Tables

An evidence profile table was used to summarise both the quality of the evidence and the results of the evidence synthesis. Each table included details about the quality assessment of each outcome: number of studies, the study design, limitations (based on the quality of individual studies; see Appendix 10 of the original guideline document for the quality checklists and Appendix 15 for details about each study), information about the consistency of the evidence (see "Quality of Evidence" in the "Rating Scheme for the Strength of the Evidence" field), directness of the evidence (that is, how closely the outcome measures, interventions and participants match those of interest) and any other considerations (for example, effect sizes with wide confidence intervals [CIs] would be described as imprecise data). Each evidence profile also included a summary of the findings: number of patients included in each group, an estimate of the magnitude of the effect, and quality of the evidence.

Forest Plots

Forest plots were used to present the results of the meta-analyses to the GDG (see Appendix 16 of the original guideline document). Each forest plot displayed the effect size and CI for each study, as well as the overall summary statistic. (See Section 4.5.4 of the original guideline document for more details.)

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Guideline Development Group (GDG)

The GDG consisted of: two service users and a carer, and professionals from psychiatry, clinical psychology, pharmacology, toxicology, nursing, general practice, the Prison Service, and the private and voluntary sectors. The guideline development process was supported by staff from the National Collaborating Centre for Mental Health (NCCMH), who undertook the clinical literature searches, reviewed and presented the evidence to the GDG, managed the process, and contributed to drafting the guideline.

Guideline Development Group Meetings

Nine GDG meetings were held between January 2006 and April 2007. During each day-long GDG meeting, in a plenary session, clinical questions and clinical and economic evidence were reviewed and assessed, and recommendations formulated. At each meeting, all GDG members declared any potential conflicts of interest, and service user and carer concerns were routinely discussed as part of a standing agenda.

Topic Groups

The GDG divided its workload along clinically relevant lines to simplify the guideline development process, and GDG members formed smaller topic groups to

undertake guideline work in that area of clinical practice. Topic group 1 covered questions relating to pharmacology and physical treatments. Topic group 2 covered psychosocial treatments, topic group 3 covered inpatient and prison settings, and topic group 4 covered testing methods. These groups were designed to efficiently manage the large volume of evidence appraisal prior to presenting it to the GDG as a whole. Each topic group was chaired by a GDG member with expert knowledge of the topic area (one of the healthcare professionals). Topic groups refined the clinical questions and the clinical definitions of treatment interventions, reviewed and prepared the evidence with the systematic reviewer before presenting it to the GDG as a whole and helped the GDG to identify further expertise in the topic. Topic group leaders reported the status of the group's work as part of the standing agenda. They also introduced and led the GDG discussion of the evidence review for that topic and assisted the GDG Chair in drafting that section of the guideline relevant to the work of each topic group.

Forming the Clinical Summaries and Recommendations

The included study tables, forest plots, and evidence profiles formed the basis for developing the evidence summaries and recommendations.

For intervention studies, quality assessment was conducted using Scottish Intercollegiate Guidelines Network (SIGN) methodology and classified according to a hierarchy (see "Rating Scheme for the Strength of the Evidence" field).

Once the evidence profile tables and evidence summaries were finalised and agreed by the GDG, recommendations were developed, taking into account factors from the evidence, including trade-offs between the benefits and risks of treatment. Other important factors that were considered in developing recommendations included economic considerations, values of the GDG and society, and the group's awareness of practical issues.

Consensus Method Used to Answer a Key Question in the Absence of Appropriately Designed, High-Quality Research

In the absence of level I evidence (or a level that is appropriate to the question), or where the GDG were of the opinion (on the basis of previous searches or their knowledge of the literature) that there was unlikely to be such evidence, a consensus process was adopted. This process focused on those questions that the GDG considered a priority.

The starting point for the process of consensus was that a member of the topic group identified, with help from the systematic reviewer, a narrative review that most directly addressed the key question. Where this was not possible, a brief review of the recent literature was initiated.

This existing narrative review or new review was used as a basis for beginning an iterative process to identify lower levels of evidence relevant to the clinical question and to lead to written statements for the guideline. Refer to Section 4.5.6 of the full version of the original guideline document for details of the steps involved in this process.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Systematic Economic Literature Review

The aim of the economic literature review was to contribute to the guideline's development by providing evidence on the relative cost effectiveness of different treatment options covered in the guideline. This process had two stages:

- Identification of the areas with likely major cost impacts within the scope of the guideline
- Systematic review of existing evidence on the cost effectiveness of different psychosocial treatment options for problem drug misuse.

In areas with likely major resource implications where economic evidence did not already exist, economic modelling was undertaken alongside the guideline development process, in order to provide cost effectiveness evidence and assist decision making.

Key Economic Issues

The following areas relating to the management of drug misuse were identified by the GDG in collaboration with the health economist as primary key issues that should be considered in the guideline:

- Cost-effectiveness of contingency management in opiate detoxification
- Cost effectiveness of various settings for detoxification

Data Extraction

Data were extracted by the health economist using a standard economic data extraction form (Appendix 13 of the original guideline document).

Presentation of the Results

The economic evidence identified by the health economics systematic review is summarised in the respective chapters of the guideline, following presentation of the clinical evidence. The characteristics and results of all economic studies included in the review are provided in the form of evidence tables in Appendix 14 of the original guideline document. Results of additional economic modelling undertaken alongside the guideline development process are also presented in the relevant chapters.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence [NICE] guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

General Considerations

Providing Information, Advice, and Support

Detoxification should be a readily available treatment option for people who are opioid dependent and have expressed an informed choice to become abstinent.

In order to obtain informed consent, staff should give detailed information to service users about detoxification and the associated risks, including:

- The physical and psychological aspects of opioid withdrawal, including the duration and intensity of symptoms, and how these may be managed
- The use of non-pharmacological approaches to manage or cope with opioid withdrawal symptoms
- The loss of opioid tolerance following detoxification, and the ensuing increased risk of overdose and death from illicit drug use that may be potentiated by the use of alcohol or benzodiazepines
- The importance of continued support, as well as psychosocial and appropriate pharmacological interventions, to maintain abstinence, treat comorbid mental health problems, and reduce the risk of adverse outcomes (including death)

Service users should be offered advice on aspects of lifestyle that require particular attention during opioid detoxification. These include:

- A balanced diet
- Adequate hydration
- Sleep hygiene
- Regular physical exercise

Staff who are responsible for the delivery and monitoring of a care plan should:

- Develop and agree the plan with the service user

- Establish and sustain a respectful and supportive relationship with the service user
- Help the service user to identify situations or states when he or she is vulnerable to drug misuse and to explore alternative coping strategies
- Ensure that all service users have full access to a wide range of services
- Ensure that maintaining the service user's engagement with services remains a major focus of the care plan
- Review regularly the care plan of a service user receiving maintenance treatment to ascertain whether detoxification should be considered
- Maintain effective collaboration with other care providers

People who are opioid dependent and considering self-detoxification should be encouraged to seek detoxification in a structured treatment programme or, at a minimum, to maintain contact with a drug service.

Service users considering opioid detoxification should be provided with information about self-help groups (such as 12-step groups) and support groups (such as the Alliance); staff should consider facilitating engagement with such services.

Staff should discuss with people who present for detoxification whether to involve their families and carers in their assessment and treatment plans. However, staff should ensure that the service user's right to confidentiality is respected.

In order to reduce loss of contact when people who misuse drugs transfer between services, staff should ensure that there are clear and agreed plans to facilitate effective transfer.

All interventions for people who misuse drugs should be delivered by staff who are competent in delivering the intervention and who receive appropriate supervision.

People who are opioid dependent should be given the same care, respect, and privacy as any other person.

Supporting Families and Carers

Staff should ask families and carers about, and discuss concerns regarding, the impact of drug misuse on themselves and other family members, including children. Staff should also:

- Offer family members and carers an assessment of their personal, social, and mental health needs
- Provide verbal and written information and advice on the impact of drug misuse on service users, families, and carers
- Provide information about detoxification and the settings in which it may take place
- Provide information about self-help and support groups for families and carers

Assessment

Clinical Assessment

People presenting for opioid detoxification should be assessed to establish the presence and severity of opioid dependence, as well as misuse of and/or dependence on other substances, including alcohol, benzodiazepines, and stimulants. As part of the assessment, healthcare professionals should:

- Use urinalysis to aid identification of the use of opioids and other substances; consideration may also be given to other near-patient testing methods such as oral fluid and/or breath testing
- Clinically assess signs of opioid withdrawal where present (the use of formal rating scales may be considered as an adjunct to, but not a substitute for, clinical assessment)
- Take a history of drug and alcohol misuse and any treatment, including previous attempts at detoxification, for these problems
- Review current and previous physical and mental health problems, and any treatment for these
- Consider the risks of self-harm, loss of opioid tolerance, and the misuse of drugs or alcohol as a response to opioid withdrawal symptoms
- Consider the person's current social and personal circumstances, including employment and financial status, living arrangements, social support, and criminal activity
- Consider the impact of drug misuse on family members and any dependants
- Develop strategies to reduce the risk of relapse, taking into account the person's support network

If opioid dependence or tolerance is uncertain, healthcare professionals should, in addition to near-patient testing, use confirmatory laboratory tests. This is particularly important when:

- A young person first presents for opioid detoxification
- A near-patient test result is inconsistent with clinical assessment
- Complex patterns of drug misuse are suspected

Near-patient and confirmatory testing should be conducted by appropriately trained healthcare professionals in accordance with established standard operating and safety procedures.

Special Considerations

Opioid detoxification should not be routinely offered to people:

- With a medical condition needing urgent treatment
- In police custody, or serving a short prison sentence or a short period of remand; consideration should be given to treating opioid withdrawal symptoms with opioid agonist medication
- Who have presented to an acute or emergency setting; the primary emergency problem should be addressed and opioid withdrawal symptoms treated, with referral to further drug services as appropriate.

For women who are opioid dependent during pregnancy, detoxification should only be undertaken with caution.

For people who are opioid dependent and have comorbid physical or mental health problems, these problems should be treated alongside the opioid dependence, in line with relevant National Institute for Health and Clinical Excellence (NICE) guidance where available.

People Who Misuse Benzodiazepines or Alcohol in Addition to Opioids

If a person presenting for opioid detoxification also misuses alcohol, healthcare professionals should consider the following.

- If the person is not alcohol dependent, attempts should be made to address their alcohol misuse, because they may increase this as a response to opioid withdrawal symptoms, or substitute alcohol for their previous opioid misuse.
- If the person is alcohol dependent, alcohol detoxification should be offered. This should be carried out before starting opioid detoxification in a community or prison setting, but may be carried out concurrently with opioid detoxification in an inpatient setting or with stabilisation in a community setting.

If a person presenting for opioid detoxification is also benzodiazepine dependent, healthcare professionals should consider benzodiazepine detoxification. When deciding whether this should be carried out concurrently with, or separately from, opioid detoxification, healthcare professionals should take into account the person's preference and the severity of dependence for both substances.

Pharmacological Interventions in Opioid Detoxification

The Choice of Medication for Detoxification

Methadone or buprenorphine should be offered as the first-line treatment in opioid detoxification. When deciding between these medications, healthcare professionals should take into account:

- Whether the service user is receiving maintenance treatment with methadone or buprenorphine; if so, opioid detoxification should normally be started with the same medication
- The preference of the service user

Lofexidine may be considered for people:

- Who have made an informed and clinically appropriate decision not to use methadone or buprenorphine for detoxification
- Who have made an informed and clinically appropriate decision to detoxify within a short time period
- With mild or uncertain dependence (including young people)

Clonidine should not be used routinely in opioid detoxification.

Dihydrocodeine should not be used routinely in opioid detoxification.

Dosage and Duration of Detoxification

When determining the starting dose, duration, and regimen (for example, linear or stepped) of opioid detoxification, healthcare professionals, in discussion with the service user, should take into account the:

- Severity of dependence (particular caution should be exercised where there is uncertainty about dependence)
- Stability of the service user (including polydrug and alcohol use, and comorbid mental health problems)
- Pharmacology of the chosen detoxification medication and any adjunctive medication
- Setting in which detoxification is conducted

The duration of opioid detoxification should normally be up to 4 weeks in an inpatient/residential setting and up to 12 weeks in a community setting.

Ultra-rapid, Rapid, and Accelerated Detoxification

Ultra-rapid and rapid detoxification using precipitated withdrawal should not be routinely offered. This is because of the complex adjunctive medication and the high level of nursing and medical supervision required.

Ultra-rapid detoxification under general anaesthesia or heavy sedation (where the airway needs to be supported) must not be offered. This is because of the risk of serious adverse events, including death.

Rapid detoxification should only be considered for people who specifically request it, clearly understand the associated risks and are able to manage the adjunctive medication. In these circumstances, healthcare professionals should ensure during detoxification that:

- The service user is able to respond to verbal stimulation and maintain a patent airway
- Adequate medical and nursing support is available to regularly monitor the service user's level of sedation and vital signs
- Staff have the competence to support airways

Accelerated detoxification, using opioid antagonists at lower doses to shorten detoxification, should not be routinely offered. This is because of the increased severity of withdrawal symptoms and the risks associated with the increased use of adjunctive medications.

Adjunctive Medications

When prescribing adjunctive medications during opioid detoxification, healthcare professionals should:

- Only use them when clinically indicated, such as when agitation, nausea, insomnia, pain, and/or diarrhoea are present
- Use the minimum effective dosage and number of drugs needed to manage symptoms

- Be alert to the risks of adjunctive medications, as well as interactions between them and with the opioid agonist

Monitoring of Detoxification Medication

Healthcare professionals should be aware that medications used in opioid detoxification are open to risks of misuse and diversion in all settings (including prisons), and should consider:

- Monitoring of medication concordance
- Methods of limiting the risk of diversion where necessary, including supervised consumption

Opioid Detoxification in Community, Residential, Inpatient, and Prison Settings

The Choice of Setting

Staff should routinely offer a community-based programme to all service users considering opioid detoxification. Exceptions to this may include service users who:

- Have not benefited from previous formal community-based detoxification
- Need medical and/or nursing care because of significant comorbid physical or mental health problems
- Require complex polydrug detoxification, for example concurrent detoxification from alcohol or benzodiazepines
- Are experiencing significant social problems that will limit the benefit of community-based detoxification

Residential detoxification should normally only be considered for people who have significant comorbid physical or mental health problems, or who require concurrent detoxification from opioids and benzodiazepines or sequential detoxification from opioids and alcohol.

Residential detoxification may also be considered for people who have less severe levels of opioid dependence, for example those early in their drug-using career, or for people who would benefit significantly from a residential rehabilitation programme during and after detoxification.

Inpatient, rather than residential, detoxification should normally only be considered for people who need a high level of medical and/or nursing support because of significant and severe comorbid physical or mental health problems, or who need concurrent detoxification from alcohol or other drugs that requires a high level of medical and nursing expertise.

Continued Treatment and Support after Detoxification

Following successful opioid detoxification, and irrespective of the setting in which it was delivered, all service users should be offered continued treatment, support,

and monitoring designed to maintain abstinence. This should normally be for a period of at least 6 months.

Delivering Detoxification

Community detoxification should normally include:

- Prior stabilisation of opioid use through pharmacological treatment
- Effective coordination of care by specialist or competent primary practitioners
- The provision of psychosocial interventions, where appropriate, during the stabilisation and maintenance phases (see section 1.5 of the original guideline document).

Inpatient and residential detoxification should be conducted with 24-hour medical and nursing support commensurate with the complexity of the service user's drug misuse and comorbid physical and mental health problems. Both pharmacological and psychosocial interventions should be available to support treatment of the drug misuse as well as other significant comorbid physical or mental health problems.

Detoxification in Prison Settings

People in prison should have the same treatment options for opioid detoxification as people in the community. Healthcare professionals should take into account additional considerations specific to the prison setting, including:

- Practical difficulties in assessing dependence and the associated risk of opioid toxicity early in treatment
- Length of sentence or remand period, and the possibility of unplanned release
- Risks of self-harm, death, or post-release overdose

Specific Psychosocial Interventions

Contingency Management to Support Opioid Detoxification

Contingency management aimed at reducing illicit drug use should be considered both during detoxification and for up to 3–6 months after completion of detoxification.

Contingency management during and after detoxification should be based on the following principles.

- The programme should offer incentives (usually vouchers that can be exchanged for goods or services of the service user's choice, or privileges such as take-home methadone doses) contingent on each presentation of a drug-negative test (for example, free from cocaine or non-prescribed opioids).
- If vouchers are used, they should have monetary values that start in the region of 2 pounds sterling and increase with each additional, continuous period of abstinence •

- The frequency of screening should be set at three tests per week for the first 3 weeks, two tests per week for the next 3 weeks, and one per week thereafter until stability is achieved.
- Urinalysis should be the preferred method of testing but oral fluid tests may be considered as an alternative.

Staff delivering contingency management programmes should ensure that:

- The target is agreed in collaboration with the service user
- The incentives are provided in a timely and consistent manner
- The service user fully understands the relationship between the treatment goal and the incentive schedule
- The incentive is perceived to be reinforcing and supports a healthy/drug-free lifestyle

Implementing Contingency Management

Drug services should ensure that as part of the introduction of contingency management, staff are trained and competent in appropriate near-patient testing methods and in the delivery of contingency management.

Contingency management should be introduced to drug services in the phased implementation programme led by the National Treatment Agency for Substance Misuse (NTA), in which staff training and the development of service delivery systems are carefully evaluated. The outcome of this evaluation should be used to inform the full-scale implementation of contingency management.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is discussed and presented in evidence tables in the relevant section of the full version of the original guideline document.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Successful withdrawal from opioid dependence
- Control of opioid dependence

POTENTIAL HARMS

Side Effects and Adverse Events

During detoxification or withdrawal from opioids, many signs and symptoms can become evident. These can be categorized broadly as due to opioid withdrawal itself or to side effects of the medication given for the detoxification regimen. During the latter stages of detoxification and in early abstinence, some signs and symptoms such as anxiety or insomnia might be the emergence of the person's "natural state." For example, a service user's opioid use may have reduced his or her levels of anxiety or insomnia, but such symptoms may re-emerge during detoxification. In addition to these, adverse events can also occur as a consequence of the medication prescribed and include events predictable from a drug's pharmacology; these can be undesirable and dangerous. It is possible that any symptom or sign could be due to any one or more of these reasons. The considerable heterogeneity amongst the studies in how withdrawal symptoms, side effects or adverse events were described and attributed makes this difficult to comment on.

Adverse Events

Adverse events are a potentially serious consequence of detoxification and may result in significant negative impact on the individual's well-being or in the individual being removed from a study (with some requiring medical attention). Significant concerns have been raised over serious adverse events, including death, especially in relation to rapid and ultra-rapid detoxification, and the sedation and anaesthesia procedures involved.

Respiratory Depression

The following applies to whenever methadone and buprenorphine are being prescribed rather than particularly referring to the process of detoxification.

As a full mu-opioid agonist, methadone can result in respiratory depression. Therefore initiation should be undertaken with care. However, some degree of tolerance to its respiratory depressive effects occurs after a period of methadone use. By contrast, buprenorphine, as a partial agonist at the mu-opioid receptor, is not associated with significant respiratory depression when taken at therapeutic doses. During detoxification and in early abstinence, it is presumed that any tolerance to respiratory depression is lost, leading to the warning about potential for 'overdose' and death from respiratory depression.

However, it is important to remember that for both methadone and buprenorphine, interactions with other respiratory depressants such as alcohol, benzodiazepines, and the newer non-benzodiazepine hypnotics (Z-drugs), other sedatives or tricyclic antidepressants may also induce serious respiratory depression. The additive or synergistic effects of such depressant drugs, particularly alcohol or benzodiazepines, may play a contributory role to deaths involving either methadone, buprenorphine or other opioid agonists. Warning individuals about "potential for overdose" should extend to include concurrent use of respiratory depressant drugs.

Severity of Withdrawal

This was generally not reported comprehensively; that is, data were rarely presented for each day over the entire duration of detoxification. The most

frequently used scales were the Subjective Opiate Withdrawal Scale and Short Opiate Withdrawal Scale. There was sparse reporting of more protracted withdrawal symptoms that may persist after completion of detoxification. In this analysis, withdrawal scores are presented as: peak (mean maximum score), lowest (mean minimum score), overall (total or mean score over the duration of detoxification) and mean change from baseline (the difference between mean overall score and mean score at baseline). Subjective rather than objective measures of withdrawal were used, as the former were judged by the Guideline Development Group (GDG) as more representative of service-user acceptability. In addition, whilst it is clearly important to use such validated withdrawal scales in trials, the GDG felt that in routine clinical practice, these scales should not replace good clinical skills or knowledge but consideration could be given to using them to complement good clinical assessment.

Special Considerations

For women who are opioid dependent during pregnancy, detoxification should only be undertaken with caution.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drugs they are considering.

Uses and Limitations of Clinical Guidelines

- Guidelines are not a substitute for professional knowledge and clinical judgement. They can be limited in their usefulness and applicability by a number of different factors: the availability of high quality research evidence, the quality of the methodology used in the development of the guideline, the generalisability of research findings and the uniqueness of individuals who misuse drugs.
- Although the quality of research in this field is variable, the methodology used here reflects current international understanding on the appropriate practice for guideline development (AGREE: Appraisal of Guidelines for Research and Evaluation Instrument; www.agreecollaboration.org), ensuring the collection and selection of the best research evidence available, and the systematic generation of treatment recommendations applicable to the majority of people with these disorders and situations. However, there will always be some people and situations for which clinical guideline recommendations are not readily applicable. This guideline does not, therefore, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual, in consultation with the person who misuses drugs/or carer.

- In addition to the clinical evidence, cost-effectiveness information, where available, is taken into account in the generation of statements and recommendations of the clinical guidelines. While national guidelines are concerned with clinical and cost effectiveness, issues of affordability and implementation costs are to be determined by the National Health Service (NHS).
- In using guidelines, it is important to remember that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for ineffectiveness. In addition, of particular relevance in mental health, evidence-based treatments are often delivered within the context of an overall treatment programme including a range of activities, the purpose of which may be to help engage the person and to provide an appropriate context for the delivery of specific interventions. It is important to maintain and enhance the service context in which these interventions are delivered; otherwise the specific benefits of effective interventions will be lost. Indeed, the importance of organising care in order to support and encourage a good therapeutic relationship is at times as important as the specific treatments offered.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health," issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

The National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance (listed below). These are available on their website (www.nice.org.uk/CG052; see also the "Availability of Companion Documents" field). The tools for these guidelines have been integrated with tools for other NICE guidance on drug misuse.

- An information briefing, which explains the implementation support available and contains links to relevant tools/documents.
- Slides highlighting key messages for local discussion.
- Costing tools
    - Costing report to estimate the national savings and costs associated with implementation.
    - Costing template to estimate the local costs and savings involved.
- Audit criteria to monitor local practice.

Key Priorities for Implementation

The following recommendations have been identified as recommendations for implementation.

Providing Information, Advice and Support

- Detoxification should be a readily available treatment option for people who are opioid dependent and have expressed an informed choice to become abstinent.
- In order to obtain informed consent, staff should give detailed information to service users about detoxification and the associated risks, including:
    - The physical and psychological aspects of opioid withdrawal, including the duration and intensity of symptoms, and how these may be managed
    - The use of non-pharmacological approaches to manage or cope with opioid withdrawal symptoms
    - The loss of opioid tolerance following detoxification, and the ensuing increased risk of overdose and death from illicit drug use that may be potentiated by the use of alcohol or benzodiazepines
    - The importance of continued support, as well as psychosocial and appropriate pharmacological interventions, to maintain abstinence, treat comorbid mental health problems and reduce the risk of adverse outcomes (including death)

The Choice of Medication for Detoxification

- Methadone or buprenorphine should be offered as the first-line treatment in opioid detoxification. When deciding between these medications, healthcare professionals should take into account:
    - Whether the service user is receiving maintenance treatment with methadone or buprenorphine; if so, opioid detoxification should normally be started with the same medication
    - The preference of the service user

Ultra-Rapid Detoxification

- Ultra-rapid detoxification under general anaesthesia or heavy sedation (where the airway needs to be supported) must not be offered. This is because of the risk of serious adverse events, including death.

The Choice of Setting for Detoxification

- Staff should routinely offer a community-based programme to all service users considering opioid detoxification. Exceptions to this may include service users who:
    - Have not benefited from previous formal community-based detoxification
    - Need medical and/or nursing care because of significant comorbid physical or mental health problems
    - Require complex polydrug detoxification, for example concurrent detoxification from alcohol or benzodiazepines
    - Are experiencing significant social problems that will limit the benefit of community-based detoxification

See Appendix C in the NICE version of the guideline (see "Availability of Companion Documents" field) for information about implementing contingency management in the NHS.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Drug misuse: opioid detoxification. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007. 276 p. (Clinical practice guideline; no. 52). [251 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Mental Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

To minimise and manage any potential conflicts of interest, and to avoid any public concern that commercial or other financial interests have affected the work of the Guideline Development Group (GDG) and influenced guidance, members of the GDG declared as a matter of public record any interests held by themselves or their families which fall under specified categories. These categories include any relationships they had with the healthcare industries, professional organisations and organisations for people who misuse drugs and their families and carers.

Individuals invited to join the GDG were asked to declare their interests before being appointed. To allow the management of any potential conflicts of interest that might arise during the development of the guideline, GDG members were also asked to declare their interests at each GDG meeting throughout the guideline development process. The interests of all the members of the GDG are listed, including interests declared prior to appointment and during the guideline development process, and are provided in Appendix 2 of the full version of the original guideline document.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

Appendices are also available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Drug misuse: opioid detoxification. NICE clinical guideline. 2007 Jul. 36 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Drug misuse: psychosocial interventions and opioid detoxification. Quick reference guide. 2007 Jul. 19 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Drug misuse: psychosocial interventions and opioid detoxification. Costing template. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2007 Jul. Various p. (Clinical guideline; no. 51). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Drug misuse: psychosocial interventions and opioid detoxification. Costing report. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2007 Jul. 42 p. (Clinical guideline; no. 51). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Misuse of drugs and other substances. Audit criteria. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2007 Nov. 20 p. (Clinical guideline; no. 51). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Misuse of drugs and other substances. Presenter slides. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2007. 47 p. (Clinical guideline; no. 51). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

- The guidelines manual 2006. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 April. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1289. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Treatments for drug misuse. Understanding NICE guidance. Information for people who use NHS services. 2007 Jul. 15 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1290. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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